REMARKS/ARGUMENTS

This Amendment and Response is promptly filed to place the above-referenced case in condition for immediate allowance.

The status of the claims is as follows:

Cancelled:	9, 10, 12-29, 40, 41, and 43-61
Amended:	None
Added:	71-75; and
Currently outstanding:	1-8, 11, 30-39, 42, 62-75

No new matter has been added to the application.

From the outstanding Office action: claims 1-8, 11, 30-32, and 62-66 stand rejected under 35 U.S.C. § 101; claims 1-8, 11, 30-39, 62-63, 66-67, and 70 stand rejected under 35 U.S.C. § 102(e); and claims 64-65 and 68-69 stand rejected under 35 U.S.C. § 103(a). The rejections based on section 102 and 103 are based upon the Lyons et al. '937 patent publication.

Reconsideration is respectfully requested. Applicant has cancelled the claims which were not elected in the prior restriction notice. Further, certain additional claims have been added in order to seek securement of subject matter available that arises from the disclosure as originally filed and which is believed to be patentable over the references cited by the Examiner. No narrowing amendment to conform with statute has been made in the application by the amendments or other changes to the claims.

The Examiner rejected claims 1 - 8, 11, 30-32, and 62-66 and 13 - 15 under 35 U.S.C. § 101. The Examiner indicated that the claims' subject matter is directed to non-statutory subject matter.

Applicant believes that the current state of the law with respect to statutory subject matter is controlled by the State Street case (State Street Bank & Trust Co. v. Signature Financial Group, 149 F.3d 1368; 47 U.S.P.Q.2d 1596 (Fed. Cir. 1998). Additionally, MPEP § 2106 deals with patentable subject matter with regards to computer related inventions as well as giving an overview to patentable subject matter. Furthermore, guidelines regarding the determination of utility have been published by the USPTO and are attached for the convenience of the Examiner. URL locations for pertinent United States Patent and Trademark Office files regarding the evaluation of utility/statutory subject matter that are available on the Internet include:

http://www.uspto.gov/web/offices/com/sol/og/2001/week05/patutil.htm;

http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf; and

http://www.uspto.gov/web/offices/pac/dapp/ogsheet.html.

Applicant notes that his claims are directed to a method, or process, of scheduling and delivery of an ordered product and includes the dispatching of a portable locker station to the pickup point, the pickup point being generally determined by the route information supplied by a buyer. Nothing in claim 1, or in any of the other claims rejected under 35 U.S.C. § 101, appear to be outside the scope of patentable subject matter which explicitly includes methods. The Examiner may want to note that three of the references cited in the pending Office action (Moreno '515, Terada et al. '914, and Lyons et al. '937) all include method claims in a form

much like those set forth in Applicant's application as amended. Applicant believes that his claims set forth clearly patentable subject matter under 35 U.S.C. § 101 as methods and processes are patentable subject matter.

Applicant believes that any talismanic reliance on "technological arts" in evaluating patentable subject matter of claims by the Examiner is misplaced and begs the questions of what are technological arts and who decides what they are. The answers to these questions have been supplied by Congress in 35 U.S.C. § 101 which sets forth what subject matters may be subject to patent (as long as all other criteria are met). There is no "technological arts" criteria in 35 U.S.C. § 101. Methods and processes are patentable subject matter per 35 U.S.C. § 101. It is not within the purview of the Patent Office or its examining corps to evaluate the technical or commercial merit of the applications presented to it, but only to ensure that the statutory criteria have been met.

As set forth herein, Applicant not only meets those criteria of 35 U.S.C. § 101, but also those of 35 U.S.C. §§ 102 and 103.

Applicant invites the Examiner to contact the undersigned with regards to the statutory nature of the subject matter should further discussion be warranted.

Applicant's invention is achieved by the following steps: 1) receiving route information from a buyer, the route information including beginning of route and end of route information; 2) generating a user travel route by using the beginning and end route information; 3) selecting a pick up location based on the travel route; and 4) dispatching a mobile pick up station (or portable locker) to the pick up point, the pick up station (or portable locker) containing the ordered product. The mobile pickup station is mobile in nature.

None of the above steps in Applicant's invention are taught by the Lyons et al. '937 patent publication (the "Lyons reference"). These novel features produce new and unexpected results, e.g., more efficient, more convenient and more cost saving results, not achievable nor suggested by the Lyons reference.

Examples of such new and unexpected results are as follows:

A) In the current claims as amended, Applicant's (Yang's) model uses a mobile pickup station (MPS) to perform delivery functions. An MPS is mobile in nature and carries many user orders simultaneously and may park at any location waiting a user to come and pick up his/her orders. The MPS is transportation equipment, i.e., it is loaded with user a user order and carries a user's order to a pickup location. But at the same time it is a storage device, i.e., it stays at the pickup location waiting for a user to pickup the order and has the storage function of a store. In the Lyons reference model, a pickup location is a store or outlet (see at least Lyons reference, paragraph 0024, line 4; paragraph 0026, line 15; paragraph 28, line 2) and is a fixed structure. Nowhere in the Lyons reference is there a suggestion that a pickup point may be mobile. Therefore, an MPS has more functions than a Lyons pickup location. The mobility feature of an MPS is more cost efficient and convenient then a fixed store as used in the Lyons reference. The pickup unit in a Lyons model is a store or outlet and is normally under a long-term commitment to operate. They are either more costly and time consuming to build or to buy, or, if the store or outlet is a leased property, it usually under a lease that requires a long-term commitment. So, when the customer demographic information changes, the Applicant MPS of the present system can easily move to a new location to accommodate the change with virtually no cost involved, a significant advantage. By contrast, in Lyons a

reference model, the server has to sell the original premises and buy or lease a new one to ,or, the server has to wait until the lease expires and then buy or lease another premises from which operate. In both cases, the Lyons model is very costly when accommodating such change.

B) In the claims of the Applicant's system under current examination, the user and seller negotiate a location where the server delivers the goods and the buyer goes to pickup the order (step 1-3 listed above). A typical pickup location is neither the seller's store nor the buyer's travel destination but somewhere near the user's travel route, after a routine travel route. The "somewhere" can be any place along the user-travel route as long as an MPS can park thereabouts. The negotiation process starts with the user's providing of his/her beginning and end travel route address. The system then uses this information to calculate a default travel route. The user may change the route to whatever the user prefers. Once the user's preferred route is determined, a pickup location that is defined by the route is selected. An MPS is then dispatched to the pickup location to await the user to pick the order. This process guarantees selection of a pickup location that is near a user's route for the user to use to thereby provide maximum convenience for a user.

The Lyons reference never discloses how to define a beginning or end of travel route. This is essential to define a route. Nor does the Lyon reference teach how to define a route based on this information. Nor does Lyon reference teach how to select a pickup location based on the user travel route. Therefore, the Lyons model can not guarantee selection of a pickup location that is near a user's route for the user to use. In the Lyons model, a user may

be forced to pick up the order by traveling away from his/her travel route, which is inconvenient compared to the present system in Applicant's model.

C) In Applicant's model, the user's travel routes are clearly defined. By using these defined user routes, Applicant's model may provide one or more overlaps of all user travel routes to identify the overlapped section(s) of users' travel routes. Since the overlapped section(s) is the portion of travel route commonly traveled through by all users, one delivery of all user orders to the overlapped section may complete delivery to all users. It is obvious that this feature allows the server to save delivery costs due to the economics of scale. It is also obvious that while the server may save costs by using the overlapping function, a user does not have to lose the ease of picking up his order because the overlapped section is where the user will travel through, just like other users do, when commuting. The Lyons model does not disclose a clear definition of a user route and/or how to build or achieve such a route. In the Lyons model, this overlapping technique can not be achieved. Of course, the Lyons model does not disclose such an overlapping feature.

In the Lyons model, there must be many users who are commuting every day and many of them must share a common section of a travel route every day. In the Lyons model, a server has no way of collecting and can not make use of this travel information to cut delivery costs and, at the same time, to maintain the convenience of picking up orders by the user, as can be done in the Applicant model, as by selecting a common pickup location.

D) The Applicant's model allows the user to clearly define a channel. The channel defines a distance away from a user's preferred travel route the user is willing to travel to pick up his/her order. The Applicants system then selects a pickup location within this channel for

the user to pick up his/her order. In Applicant's model, every pick up location selected is convenient to a user. This channeling technique can only be achieved when a user's travel route can be clearly defined. Lyons's model does not provide such a function. It is then possible that in Lyons's model, a user may pick up an order by traveling to a pick up location that is too faraway for the user. Applicant's model is therefore much convenient to users than Lyons.

Per the above, Applicant Yang believes that the Lyons et al. reference does not anticipate Applicant's claims. In paragraph 6 of the action, the examine relief upon Figure 2, paragraphs 0007-0008, 0023-0024 and 0054-0056 of the Lyons reference and asserts that Lyons system teaches "a method for scheduling and delivery of a product to a buyer along the buyer's commuting route, comprising: receiving route information from the buyer".

The "route information" in Applicant's invention pertains to a user's travel route information and may be defined by the beginning point and an end point of user's travel path. In Applicant's model, a user travel route is communicated to and is saved formulated in the server's system so that the server may make use of it. For example, the travel route information is saved in the server system so that the server may use this information to select a location near the traveling path, to park an MPS and make it a pickup location (See Applicant's disclosure in the patent application, invention, at least at paragraphs 0042, 0051, 0053, 0054, 0035, 0056 and others. Other uses of such route information include overlapping and channeling as discussed before.

In the Lyons system, a user travels to a pickup location to pickup an order. The user travel path information is never communicated to the server, is never formulated in the

server's system, can never be made of use by the server, and is unnecessary to the server. In Lyons's invention, the only teaching regarding route information and the route information is within the server's system appears in paragraph 0028, where it states, "Once the purchasing system 10 has received and processed the order, the order is routed to a particular store or outlet of a seller" (emphasis added). But the "route information" referred to here refers to the traveling of the goods, or order not the traveling of the user as referred to in Applicant's model. The Lyons reference never disclose a user travel route that may be communicated to the server, nor does it disclose how to define a beginning and an end of such a user travel route and/or how to build such a user travel route.

With respect to the Examiner's assertion that the Lyon reference discloses a step of selecting from a plurality of pickup points, a pickup point based on the route information, Figure 2 sets forth a flow chart that has the seller selling the goods at a specific pickup station, but nowhere is it disclosed that the pickup point was selected from a plurality of pickup points nor are either the plurality of pickup points or the individual pickup point based on the route information. This is particularly true as there is no route information is set forth, determined, or indicated in the Lyons '937 publication.

Nothing in the additional paragraphs cited by the Examiner paragraphs 7-8, 23-24 and 54-56 resolve the absence of route information enabling the indication of a plurality of pickup points where by a single pickup may be selected from that plurality.

With respect to the Examiner's assertion that the step of dispatching a mobile pickup station to a pickup point where the mobile pickup point contains a product ordered by the buyer, Figure 2 makes no such disclosure and step 124 indicates the buyer arrives at the pickup

station to collection goods but nowhere does it say that the pickup station goes to a certain location in order to meet the buyer. Additionally, and as for the previous assertion with respect to selecting from a plurality of pickup points above, paragraphs 54-56 do nothing to indicate that delivery of the goods by the seller to the buyer. The buyer in the Lyons et al. system, never indicates a route, path of travel, or anything other than a specific pickup point which may have an infinite number of routes depending upon the initial location of the buyer. As a result, the specific elements in Applicant's claim 1 do not find a one-to-one correspondence with one or more elements in the Lyons '937 reference. This is required for anticipation under 35 U.S.C. § 102. Additionally, Lyons et al. '937 reference does not make obvious Applicant's claim 1 as there is no motivation, indication, teaching, or instruction that would allow a person, particularly a person of ordinary skill in the art, to take the Lyons et al. '937 reference and achieve Applicant's claim 1.

There is no teaching, indication, motivation, instruction or disclosure with respect to the selection of a route, or the opportunity to select a single pickup point from a plurality of pickup points accessible by such a route. The Examiner cannot engage in wishful thinking and use Applicant's disclosure as a map by which Applicant's claims can be rejected. The only map the Examiner can use is that which is provided by the prior art, and not Applicant's disclosure. Applicants are given the benefit of the doubt when they come before the Patent Office and cannot have their own disclosure used against them. No matter how simple or complex the technology, the burden of rejection always lies with the Patent Office in order to show that the prior art (and not Applicant's disclosure) provides the basis for rejecting

Applicant's claims as either being anticipated or obvious. In re Dembiczak, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

As the Lyons et al. '937 reference does not rely on, use, require, disclose, or even benefit from the use of disclosure of route information. There is no teaching, indication, motivation, or disclosure with regards to such route information. As a result, the Lyons et al. reference cannot anticipate or make obvious Applicant's claim 1

Consequently, claim 1 is allowable over the Lyons et al. '937 reference as are those claims dependent upon it, claims 2-8, 62-66, and 71-72.

The Examiner rejected claim 11 as anticipated by the Lyons et al. reference. However, as indicated above, the Lyons '937 reference does not disclose the use of route information, nor the selection of a pickup point based on such route information, nor the selection of a pickup point selected from a plurality of pickup points based on the route information. Consequently, claim 11 is neither anticipated nor made obvious by the Lyons et al. '937 reference.

As claim 11 is patentable over the Lyons et al. '937 reference, claim 73 is also patentable as it depends upon claim 11.

With respect to Applicant's claim 30, route information is received from a buyer according to Applicant's claim 30. A channel area is calculated using a channel width indication from the buyer. A set of pickup points includes a set of plurality of points based upon the channel area. A single pickup point is selected from other pickup points. The mobile pickup station that contains the product ordered by the buyer is then dispatched to the pick up point.

The Examiner has rejected Applicant's claim 30 based on the Lyons et al. '937 reference. As set forth above, the Lyons et al. '937 does not teach anything about route information and so the Lyons '937 reference cannot anticipate, nor make obvious Applicant's claim 30 as set forth above with respect to Applicant's claim 1.

As Applicant's claim 30 is neither anticipated nor made obvious by Lyon, et al. those claims that depend upon claim 30 are also not anticipated nor made obvious by the Lyons et al. reference. These claims are claims 31, 32 and 74.

Applicant's claim 33 discloses a data processing system adapted to scheduling and delivering a product to a buyer along the buyer's commuting route. The data processing system receives route information from a buyer via its program instructions. A pickup point based on the route information supplied by the buyer is selected from a plurality of pickup points. A mobile pickup station is dispatched to that route-based pickup point, the mobile pickup station containing a product ordered by the buyer.

As set forth above, the Lyons et al. '937 reference discloses nothing about route information and so cannot anticipate or make obvious Applicant's claim 33.

Additionally, those claims that depend upon claim 33 are also neither anticipated nor made obvious by the Lyons et al. '937 reference. These claims include claims 34-39, 67-70 and 75.

With respect to Applicant's claim 42, a data processing system adapted to schedule and delivered a product to a buyer using a third party seller affiliate is disclosed that comprises a processor executing instructions. The program instructions include receiving route information from a buyer, selecting a route-based pickup point based on the plurality of pickup points,

selecting a third party seller affiliate according to the route-based pickup point, dispatching a mobile pick up station to the third party seller affiliate selected according to the route-based pickup point with the mobile pickup station containing the products ordered by the buyer.

As set forth above, the Lyons et al. 937 reference contains no information, disclosure, or indication of route-gathering or route basing activity. As a result, the Lyons et al '937 reference cannot anticipate nor make obvious Applicant's claim 42 along the lines set forth above with regards to the claims previous discussed above.

In view of the above, the Examiner is respectfully requested to reconsider his position in view of the remarks made herein and the structural distinctions now set forth. The Examiner's rejection of the outstanding claim are believed to no longer apply. It is now believed that this application has been placed in condition for allowance, and such action is respectfully requested. Prompt and favorable action on the merits is earnestly solicited. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The statements made herein with respect to the disclosures in the cited references represent the present opinions of the undersigned attorney. In the event that the Examiner disagrees with any of such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the respective references providing the basis for a contrary view.

If the Examiner believes that a telephone or other conference would be of value in expediting the prosecution of the present application, enabling an Examiner's amendment or other meaningful discussion of the case, Applicant invites the Examiner to contact Applicant's representative at the number listed below.

With the above-referenced changes, it is believed that the application is in a condition for allowance; and Applicant respectfully requests the Examiner to pass the application on to allowance. It is not believed that any additional fees are due; however, in the event any additional fees are due, the Examiner is authorized to charge Applicant's Attorney's Deposit Account No. 03-2030.

Respectfully submitted,

CISLO & THOMAS LLP

Date: March 22, 2005

Donald M. Cislo
Reg. No. 22,060
Tel.: (310) 451-0647 x123

Enclosures
Examination Guidelines (2)
Petition for Extension of Time 1 Month
Acknowledgement Postcard

CISLO & THOMAS LLP
233 Wilshire Boulevard, Suite 900
Santa Monica, California 90401
Tel: (310) 451-0647
Fax: (310) 394-4477
Customer No.: 25,189
www.cislo.com

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March 21, 2005

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027289-0263-02]

RIN 0651-AB09

Utility Examination Guidelines

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the `utility' requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Nagumo by telephone at (703) 305-8666, by facsimile at (703) 305-9373, by electronic mail at `mark.nagumo@uspto.gov,' or by mail marked to his attention addressed to the Office of the Solicitor, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305-9323, by facsimile at (703) 305-8825, by electronic mail at `linda.therkorn@uspto.gov,' or by mail marked to her attention addressed to Box Comments, Commissioner for Patents, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the `utility' requirement of 35 U.S.C. 101. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

I. Discussion of Public Comments

The Revised Interim Utility Examination Guidelines published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67, Feb. 15, 2000, requested comments from the public. Comments were received from 35 individuals and 17 organizations. The written comments have been carefully considered.

Overview of Comments

The majority of comments generally approved of the guidelines and several expressly stated support for the three utility criteria (specific, substantial, and credible) set forth in the Guidelines. A few comments addressed particular concerns with respect to the coordinate examiner training materials that are available for public inspection at the USPTO website, www.uspto.gov. The comments on the training materials will be taken under advisement in the revision of the training materials. Consequently, those comments are not specifically addressed below because they do not impact the content of the Guidelines. Comments received in response to the request for comments on the `Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 `Written

Description' Requirement,' 64 FR 71427, Dec. 21, 1999; 1231 O.G. 123, Feb. 29, 2000, which raised issues pertinent to the utility requirement are also addressed below.

Responses to Specific Comments

(1) Comment: Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. Response: The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S. Constitution uses the word `discoveries' where it authorizes Congress to promote progress made by inventors. The pertinent part of the Constitution is Article 1, section 8, clause 8, which reads: `The Congress shall have power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who `invents or discovers' a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: `Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, orany new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.' Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the `utility' requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

(2) Comment: Several comments state that a gene is not a new composition of matter because it exists in nature, and/or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement. Response: The comments are not adopted. A patent claim directed to an isolated and purified DNA molecule could cover, e.g., a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound. Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming `[y]east, free from organic germs of disease, as an article of manufacture.' Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: `even if it were merely an extracted product without change, there is no rule that such products are not

patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.' Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE2 and PGE3, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that `inasmuch as the `claimed compounds are naturally occurring' * * * they therefore `are not lnew' within the connotation of the patent statute.'' In re Bergstrom, 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: `what appellants claimMpure PGE2 and PGE3Mis not `naturally occurring.' Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist.' Id. at 1401, 166 USPQ at 261-62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body `includes' a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form. When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline.

(3) Comment: Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter. Response: The suggestion is not adopted. Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended `anything under the sun that is made by man' to be eligible for patenting. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court interprets the statute to cover a `nonnaturally occurring manufacture or composition of matter-a product of human ingenuity.' Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980). Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information. While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability.

(4) Comment: Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. Other comments stated that patents should be for marketable inventions and not for discoveries in nature. Response: The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale,

selling, or importing the composition for a limited time. That is, a patent owner can stop infringing activity by others for a limited time.

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. `[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish `usefulness' within the meaning of 101.' In re Langer, 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have met the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transfor into new and useful products are eligible for patents.

(5) Comment: Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued. Response: The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) Comment: One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's Diamond v. Chakrabarty decision was a bare 5-to-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/ research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes. Response: The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment. The USPTO must administer the patent statutes as the Supreme Court interprets them. When Congress enacted 101, it indicated that `anything under the sun that is made by man' is subject matter for a patent. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court has interpreted 101 many times without overturning it. See, e.g., Diamond v. Diehr, 450 U.S. 175, 209 USPQ 1 (1981) (discussing cases construing section 101). Under United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35. Thus, ESTs which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention.

(7) Comment: Several comments state that patents should not issue for genes because patents on genes are delaying ical research and thus there is

no societal benefit associated with gene patents. Others state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development. Some comment that patentees will deny access to genes and our property (our genes) will be owned by others. Response: The comments are not adopted. The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development. The patent statutes provide that a patent must be granted when at least one specific, substantial and credible utility has been disclosed, and the application satisfies the other statutory requirements. As long as one specific, substantial and credible use is disclosed and the statutory requirements are met, the USPTO is not authorized to withhold the patent until another, or better, use is discovered. Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides. A patent grants exclusionary rights over a patented composition but does not grant ownership of the composition. Patents are not issued on compositions in the natural environment but rather on isolated and purified compositions.

(8) Comment: Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility. Response: A DNA sequence-i.e., the sequence of base pairs making up a DNA moleculeMis simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA molecule isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not per se unpatentable for lack of utility, and each application claim must be examined on its own facts.

(9) Comment: One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the `basic social contract of the patent deal' requires that such a discovery should be patentable, and that patenting should be `value-blind.' Response: The comment is not adopted. The Supreme Court did not find a similar argument persuasive in Brenner v. Manson, 383 U.S. 519 (1966). The courts interpret the statutory term `useful' to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed.

(10) Comment: Several comments stated that the scope of patent claims directed to DNA should be limited to applications or methods of using DNA, and should not be allowed to encompass the DNA itself. Response: The comment is not adopted. Patentable subject matter includes both `process[es]' and `composition[s] of matter.' 35 U.S.C. 101. Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter. If a patent application claims a composition of matter comprising DNA, and the claims meet all the statutory requirements of patentability, there is no legal basis for rejecting the application.

(11) Comment: Several comments stated that DNA patent claim scope should be limited to uses that are disclosed in the patent application and that allowing patent claims that encompass DNA itself would enable the inventor to assert claimedms to `speculative' uses of the DNA that were not foreseen

at the time the patent application was filed. Response: The comment is not adopted. A patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from any method of using that DNA composition, for up to 20 years from the filing date. This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, inter alia, `using' the patented composition of matter. See 35 U.S.C. 154. Where a new use is discovered for a patented DNA composition, that new use may qualify for its own process patent, notwithstanding that the DNA composition itself is patented.

By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established utility, the examiner will reject the claim under section 101. The rejection shifts the burden to the applicant to show that the examiner erred, or that a well-established utility would have been readily apparent to one of skill in the art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. See, e.g., In re Wright, 999 F.2d 1557, 1562-63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993) (`developments occurring after the filing date of an application are of no significance regarding what one skilled in the art believed as of the filing date').

(12) Comment: Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits bioical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good. Response: The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. `Whoever invents or discovers any new and useful * * * composition of matter * * * may obtain a patent therefor.' 35 U.S.C. 101. Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

(13) Comment: Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive. Response: The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a `composition of matter,' one of the four classes of invention authorized by 35 U.S.C. 101. A DNA molecule must be nonobvious in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. See 35 U.S.C. 103(a) (`Patentability shall not be negatived by the manner in which the invention was made.'). As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular structure

of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. See, e.g., In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) (`[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious.'); see also, In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(14) Comment: One comment suggested that genes ought to be patentable only when the complete sequence of the gene is disclosed and a function for the gene product has been determined. Response: The suggestion is not adopted. To obtain a patent on a chemical compound such as DNA, a patent applicant must adequately describe the compound and must disclose how to make and use the compound. 35 U.S.C. 101, 112. `An adequate written description of a DNA * * * requires a precise definition, such as by structure, formula, chemical name, or physical properties.' Univ. of California v. Eli Lilly & Co., 119 F.3d 1559, 1556, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added, internal quote omitted). Thus, describing the complete chemical structure, i.e., the DNA sequence, is one method of describing a DNA molecule but it is not the only method. In addition, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, e.g., it hybridizes near a disease-associated gene or it has a gene- regulating activity.

(15) Comment: One comment stated that the specification should `disclose the invention,' including why the invention works and how it was developed. Response: The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, 1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. `[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.' Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

(16) Comment: One comment suggested that patents should `allow for others to learn from and improve the invention.' The comment suggested that claims to patented plant varieties should not prohibit others from using the patented plants to develop improved varieties. The comment also stated that uses of plants in speculative manners should not be permitted. Response: By statute, a patent provides the patentee with the right to exclude others from, inter alia, making and using the claimed invention, although a limited research exemption exists. See 35 U.S.C. 163, 271(a), (e). These statutory provisions are not subject to revision by the USPTO and are not affected by these Guidelines. Where a plant is claimed in a utility patent application, compliance with the statutory requirements for utility under 35 U.S.C. 101 only requires that a claimed invention be supported by at least one specific, substantial and credible utility. It is somewhat rare for academic researchers to be sued by commercial patent owners for patent infringement. Most inventions are made available to academic researchers on very favorable licensing terms, which enable them to continue their research.

(17) Comment: Two comments suggested that although the USPTO has made a step in the right direction in raising the bar in the Utility Guidelines, there is still a need to apply stricter standards for utility. Response: The USPTO is bound by 35 U.S.C. 101 and the case law interpreting 101. The Guidelines reflect the USPTO's understanding of 101.

(18) Comment: Several comments addressed specific concerns about the examiner training materials. Response: The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials. Except for comments with regard to whether sequence homology is sufficient to demonstrate a specific and substantial credible utility, specific concerns about the training materials will not be addressed herein as they will not impact the language of the guidelines.

(19) Comment: Several comments suggested that the use of computer-based analysis of nucleic acids to assign a function to a given nucleic acid based upon homology to prior art nucleic acids found in databases is highly unpredictable and cannot form a basis for an assignment of function to a putatively encoded protein. These comments also indicate that even in instances where a general functional assignment may be reasonable, the assignment does not provide information regarding the actual biological activity of an encoded protein and therefore patent claims drawn to such nucleic acids should be limited to method of use claims that are explicitly supported by the as-filed specification(s). These comments also state that if homology-based utilities are acceptable, then the nucleic acids, and proteins encoded thereby, should be considered as obvious over the prior art nucleic acids. On the other hand, one comment stated that homology is a standard, art- accepted basis for predicting utility, while another comment stated that any level of homology to a protein with known utility should be accepted as indicative of utility. Response: The suggestions to adopt a per se rule rejecting homology-based assertions of utility are not adopted. An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112). When the USPTO denies a patent, the Office must set forth at least a prima facie case as to why an applicant has not met the statutory requirements. The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' per se rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. See, e.g., In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did `not suggest an inherently unbelievable undertaking or involve implausible scientific principles' and where `prior art * * * discloses structurally similar compounds to those claimed by the applicants which have been proven * * * to be effective').

A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. `[A] `rigorous correlation' need not be shown in order to establish practical utility; `reasonable correlation' is sufficient.' Fujikawa v. Wattanasin, 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). The Office will take into account both the nature and degree of the homology.

When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of

sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no per se rule regarding homology, and each application must be judged on its own merits.

The comment indicating that if a homology-based utility could meet the requirements set forth under 35 U.S.C. 101, then the invention would have been obvious, is not adopted. Assessing nonobviousness under 35 U.S.C. 103 is separate from analyzing the utility requirements under 35 U.S.C. 101. When a claim to a nucleic acid supported by a homology-based utility meets the utility requirement of section 101, it does not follow that the claimed nucleic acid would have been prima facie obvious over the nucleic acids to which it is homologous. `[S]ection 103 requires a fact-intensive comparison of the [claim] with the prior art rather than the mechanical application of one or another per se rule.' In re Ochiai, 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). Nonobviousness must be determined according to the analysis in Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966). See also, In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc) (`structural similarity between claimed and prior art subject matter, * * * where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness') (emphasis added). Where `the prior art teaches a specific, structurally-definable compound [] the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.' In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

(20) Comment: Several comments indicated that in situations where a well-established utility is relied upon for compliance with 35 U.S.C. 101, the record should reflect what that utility is. One comment stated that the record should reflect whether the examiner accepted an asserted utility or relied upon a well-established utility after dismissing all asserted utilities. Another comment stated that when the examiner relies on a well-established utility not explicitly asserted by the applicant, the written record should clearly identify this utility and the rationale for considering it specific and substantial. Response: The comments are not adopted. Only one specific, substantial and credible utility is required to satisfy the statutory requirement. Where one or more well-established utilities would have been readily apparent to those of skill in the art at the time of the invention, an applicant may rely on any one of those utilities without prejudice. The record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities for related inventions. Thus, even when the examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities. Just as the examiner without comment may accept a properly asserted utility, there is no need for an examiner to comment on the

existence of a well-established utility. However, the Guidelines have been revised to clarify that a well-established utility is a specific, substantial, and credible utility that must be readily apparent to one skilled in the art. Most often, the closest prior art cited and applied in the course of examining the application will demonstrate a well-established utility for the invention.

(21) Comment: Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment states that this requires the examiner to prove a negative. Another comment states that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility. Response: The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention.

(22) Comment: Several comments suggested that further clarification was required with regard to the examiner's determination that there is an adequate nexus between a showing supporting a well-established utility and the application as filed. The comments indicated that the meaning of this `nexus' was unclear. Response: The Guidelines have been modified to reflect that evidence provided by an applicant is to be analyzed with regard to a concordance between the showing and the full scope and content of the claimed invention as disclosed in the application as filed. In situations where the showing provides adequate evidence that the claim is supported by at least one asserted specific, substantial, and credible or well-established utility, the rejections under 35 U.S.C. 101 and 112, first paragraph, will be withdrawn. However, the examiner is instructed to consider whether or not the specification, in light of applicant's showing, is enabled for the use of the full scope of the claimed invention. Many times prior patents and printed publications provided by applicant will clearly demonstrate that a well-established utility exists.

(23) Comment: One comment states that the Office is using an improper standard in assessing `specific' utility. According to the comment, a distinction between `specific' and `general' utilities is an overreaching interpretation of the specificity requirement in the case law because `unique' or `particular' utilities have never been required by the law. The comment states that the specificity requirement concerns sufficiency of disclosure, i.e., teaching how to make and use a claimed invention, not the utility requirement. The comment states that the specificity requirement is to be distinguished from the `substantial' utility requirement, and that the Brenner v. Manson decision concerned only a `substantial' utility issue, not specificity. Response: The comment is not adopted. The disclosure of only a general utility rather than a particular utility is insufficient to meet statutory requirements. Although the specificity requirement is relevant to s 112, it is not severable from the utility requirement.

[S]urely Congress intended s 112 to pre-suppose full satisfaction of the requirements of 101. Necessarily, compliance with 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention. As this court stated in Diederich, quoting with approval from

the decision of the board:

`We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.' As the Supreme Court said in Brenner v. Manson:

`* * * a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'

In re Kirk, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) (affirming rejections under 101 and 112) (emphasis in original).

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

B. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the ``useful invention' (`utility') requirement of 35 U.S.C. 101 and 112, first paragraph.

1. Read the claims and the supporting written description.

(a) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(b) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).

(c) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a ``specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on

lack of utility.

(1) A claimed invention must have a specific and substantial utility. This requirement excludes `throw-away,' `insubstantial,' or `nonspecific' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

(2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under s 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The s 112, first paragraph, rejection imposed in conjunction with a 101 rejection should incorporate by reference the grounds of the corresponding 101 rejection.

(c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(1) Explicitly identify a specific and substantial utility for the claimed invention; and

(2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(2) Support for factual findings relied upon in reaching this

conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(b) Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The prima facie showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(c) Where no specific and substantial utility is disclosed or is well-established, a prima facie showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well- stablished utility.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record. Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a prima facie showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the prima facie showing. If the applicant responds to the prima facie rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a prima facie rejection based on lack of utility under 101, withdraw the 101 rejection and the corresponding rejection imposed under 112, first paragraph.

December 29, 2000.

Q. TODD DICKINSON,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that NOAA is requesting comments on the report "Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries" and two peer reviews of this report. The report and peer reviews are available for download at http://www.sanctuaries.nos.noaa.gov/news/newsbboard/newsbboard.html or by requesting an electronic or hard copy. Requests can be made by sending an email to submarine.cables@noaa.gov (subject line "Request for Fair Market Value Analysis") or by calling Matt Brookhart at (301) 713–3125 x140.

DATES: Comments on this notice must be received by January 18, 2001.

ADDRESSES: Address all comments regarding this notice to Matt Brookhart, Conservation Policy and Planning Branch, Office of National Marine Sanctuaries, 1305 East-West Highway, 11th Floor, Silver Spring, MD 20910, Attention: Fair Market Value Analysis. Comments may also be submitted by email to: *submarine.cables@noaa.gov*, subject line "Fair Market Value Analysis."

FOR FURTHER INFORMATION CONTACT: Helen Golde, (301) 713–3125 x152.

SUPPLEMENTARY INFORMATION: The Office of National Marine Sanctuaries has issued several special-use permits to companies seeking to install fiber optic cables in National Marine Sanctuaries. The Sanctuary statute allows ONMS to permit the presence of cables on the sanctuaries' seafloor should it decide to do so. If an application is approved, ONMS may collect certain administrative and monitoring fees. In addition, ONMS is entitled to receive fair market value for the permitted use of sanctuary resources.

The report "Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries" presents an assessment of fair market value for the use of National Marine Sanctuary resources for a fiber optic cable. Proper stewardship of sanctuary resources and open and equitable relations with telecommunication industry interests require a clear and consistent policy in this matter. The content of this report is based on dozens of industry and government sources and draws on the collaboration and review of numerous experts in the business, legal and technical arenas.

Once finalized, the fee structure proposed in this report will be used to assess fees (as stated in their respective special use permits) for cables already installed in the Olympic Coast and Stellwagen Bank National Marine Sanctuaries. In addition, this structure will provide the basis for future fair market value assessment of submarine cable permit applications in National Marine Sanctuaries. Comments on the report and peer reviews should focus on the methodology employed and the conclusions that it reached.

Dated: December 29, 2000.

John Oliver,

Chief Financial Officer, National Ocean Service.

[FR Doc. 01–387 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027289–0263–02]

RIN 0651–AB09

Utility Examination Guidelines

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the "utility" requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Nagumo by telephone at (703) 305–8666, by facsimile at (703) 305–9373, by electronic mail at "mark.nagumo@uspto.gov," or by mail marked to his attention addressed to the Office of the Solicitor, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305–9323, by facsimile at (703) 305–8825, by electronic mail at "linda.therkorn@uspto.gov," or by mail marked to her attention addressed to Box Comments, Commissioner for Patents, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "utility" requirement of 35 U.S.C. 101. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

I. Discussion of Public Comments

The Revised Interim Utility Examination Guidelines published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67, Feb. 15, 2000, requested comments from the public. Comments were received from 35 individuals and 17 organizations. The written comments have been carefully considered.

Overview of Comments

The majority of comments generally approved of the guidelines and several expressly stated support for the three utility criteria (specific, substantial, and credible) set forth in the Guidelines. A few comments addressed particular concerns with respect to the coordinate examiner training materials that are available for public inspection at the USPTO website, *www.uspto.gov.* The comments on the training materials will be taken under advisement in the revision of the training materials. Consequently, those comments are not specifically addressed below because they do not impact the content of the Guidelines. Comments received in response to the request for comments on the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 'Written Description' Requirement," 64 FR 71427, Dec. 21, 1999; 1231 O.G. 123, Feb. 29, 2000, which raised issues pertinent to the utility requirement are also addressed below.

Responses to Specific Comments

(1) *Comment:* Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. *Response:* The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S.

Constitution uses the word "discoveries" where it authorizes Congress to promote progress made by inventors. The pertinent part of the Constitution is Article 1, section 8, clause 8, which reads: "The Congress shall have power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who "invents or discovers" a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

(2) *Comment:* Several comments state that a gene is not a new composition of matter because it exists in nature, and/or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement. *Response:* The comments are not adopted. A patent claim directed to an isolated and purified DNA molecule could cover, *e.g.*, a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming "[y]east, free from organic germs of disease, as an article of manufacture." Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: "even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent." *Parke-Davis & Co.* v. *H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE_2 and PGE_3, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that "inasmuch as the 'claimed compounds are naturally occurring' * * * they therefore 'are not 'new' within the connotation of the patent statute.'" *In re Bergstrom*, 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: "what appellants claim—pure PGE_2 and PGE_3—is not 'naturally occurring.' Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist." *Id.* at 1401, 166 USPQ at 261–62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body "includes" a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form. When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline.

(3) *Comment:* Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter. *Response:* The suggestion is not adopted. Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended "anything under the sun that is made by man" to be eligible for patenting. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court interprets the statute to cover a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity." *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980). Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information. While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability.

(4) *Comment:* Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. Other comments stated that patents should be for marketable inventions and not for discoveries in nature. *Response:* The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing

the composition for a limited time. That is, a patent owner can stop infringing activity by others for a limited time.

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. "[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish 'usefulness' within the meaning of § 101." *In re Langer,* 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have met the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents.

(5) *Comment:* Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued. *Response:* The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) *Comment:* One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's *Diamond* v. *Chakrabarty* decision was a bare 5-to-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes. *Response:* The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment. The USPTO must administer the patent statutes as the Supreme Court interprets them. When Congress enacted § 101, it indicated that "anything under the sun that is made by man" is subject matter for a patent. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court has interpreted § 101 many times without overturning it. *See, e.g., Diamond* v. *Diehr,* 450 U.S. 175, 209 USPQ 1 (1981) (discussing cases construing section 101). Under United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35. Thus, ESTs which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention.

(7) *Comment:* Several comments state that patents should not issue for genes because patents on genes are delaying medical research and thus there is no societal benefit associated with gene patents. Others state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development. Some comment that patentees will deny access to genes and our property (our genes) will be owned by others. *Response:* The comments are not adopted. The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development. The patent statutes provide that a patent must be granted when at least one specific, substantial and credible utility has been disclosed, and the application satisfies the other statutory requirements. As long as one specific, substantial and credible use is disclosed and the statutory requirements are met, the USPTO is not authorized to withhold the patent until another, or better, use is discovered. Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides. A patent grants exclusionary rights over a patented composition but does not grant ownership of the composition. Patents are not issued on compositions in the natural environment but rather on isolated and purified compositions.

(8) *Comment:* Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility. *Response:* A DNA sequence—*i.e.,* the sequence of base pairs making up a DNA molecule—is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, *e.g.,* it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not *per se* unpatentable for lack of utility, and each application claim must be examined on its own facts.

(9) *Comment:* One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the "basic social contract of the patent deal" requires that such a discovery should be patentable, and that patenting should be "value-blind." *Response:* The comment is not adopted. The Supreme Court did not find a similar argument persuasive in *Brenner* v. *Manson,* 383 U.S. 519 (1966). The courts interpret the statutory term "useful" to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed.

(10) *Comment:* Several comments stated that the scope of patent claims directed to DNA should be limited to applications or methods of using DNA, and should not be allowed to

encompass the DNA itself. *Response:* The comment is not adopted. Patentable subject matter includes both "process[es]" and "composition[s] of matter." 35 U.S.C. 101. Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter. If a patent application claims a composition of matter comprising DNA, and the claims meet all the statutory requirements of patentability, there is no legal basis for rejecting the application.

(11) *Comment:* Several comments stated that DNA patent claim scope should be limited to uses that are disclosed in the patent application and that allowing patent claims that encompass DNA itself would enable the inventor to assert claims to "speculative" uses of the DNA that were not foreseen at the time the patent application was filed. *Response:* The comment is not adopted. A patent on a composition gives *exclusive* rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from *any* method of using that DNA composition, for up to 20 years from the filing date. This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, *inter alia,* "using" the patented composition of matter. *See* 35 U.S.C. 154. Where a new use is discovered for a patented DNA composition, that new use may qualify for its own process patent, notwithstanding that the DNA composition itself is patented.

By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established utility, the examiner will reject the claim under section 101. The rejection shifts the burden to the applicant to show that the examiner erred, or that a well-established utility would have been readily apparent to one of skill in the art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. *See, e.g., In re Wright,* 999 F.2d 1557, 1562–63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993) ("developments occurring after the filing date of an application are of no significance regarding what one skilled in the art believed as of the filing date").

(12) *Comment:* Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good. *Response:* The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. "Whoever invents or discovers any new and useful * * * composition of matter * * * may obtain a patent therefor." 35 U.S.C. 101. Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

(13) *Comment:* Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive. *Response:* The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a "composition of matter," one of the four classes of invention authorized by 35 U.S.C. 101. A DNA molecule must be *nonobvious* in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. *See* 35 U.S.C. 103(a) ("Patentability shall not be negatived by the manner in which the invention was made."). As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular *structure* of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. *See, e.g., In re Deuel,* 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious."); *see also, In re Bell,* 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(14) *Comment:* One comment suggested that genes ought to be patentable only when the complete sequence of the gene is disclosed and a function for the gene product has been determined. *Response:* The suggestion is not adopted. To obtain a patent on a chemical compound such as DNA, a patent applicant must adequately describe the compound and must disclose how to make and use the compound. 35 U.S.C. 101, 112. "An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties." *Univ. of California* v. *Eli Lilly & Co.,* 119 F.3d 1559, 1556, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added, internal quote omitted). Thus, describing the complete chemical structure, *i.e.,* the DNA sequence, is one method of describing a DNA molecule but it is not the only method. In addition, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, *e.g.,* it hybridizes near a disease-associated gene or it has a gene-regulating activity.

(15) *Comment:* One comment stated that the specification should "disclose the invention," including why the invention works and how it was developed. *Response:* The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, ¶ 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, ¶1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman* v. *Quigg,*

877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

(16) *Comment:* One comment suggested that patents should "allow for others to learn from and improve the invention." The comment suggested that claims to patented plant varieties should not prohibit others from using the patented plants to develop improved varieties. The comment also stated that uses of plants in speculative manners should not be permitted. *Response:* By statute, a patent provides the patentee with the right to exclude others from, *inter alia,* making and using the claimed invention, although a limited research exemption exists. *See* 35 U.S.C. 163, 271(a), (e). These statutory provisions are not subject to revision by the USPTO and are not affected by these Guidelines. Where a plant is claimed in a utility patent application, compliance with the statutory requirements for utility under 35 U.S.C. 101 only requires that a claimed invention be supported by at least one specific, substantial and credible utility. It is somewhat rare for academic researchers to be sued by commercial patent owners for patent infringement. Most inventions are made available to academic researchers on very favorable licensing terms, which enable them to continue their research.

(17) *Comment:* Two comments suggested that although the USPTO has made a step in the right direction in raising the bar in the Utility Guidelines, there is still a need to apply stricter standards for utility. *Response:* The USPTO is bound by 35 U.S.C. 101 and the case law interpreting § 101. The Guidelines reflect the USPTO's understanding of § 101.

(18) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials. Except for comments with regard to whether sequence homology is sufficient to demonstrate a specific and substantial credible utility, specific concerns about the training materials will not be addressed herein as they will not impact the language of the guidelines.

(19) *Comment:* Several comments suggested that the use of computer-based analysis of nucleic acids to assign a function to a given nucleic acid based upon homology to prior art nucleic acids found in databases is highly unpredictable and cannot form a basis for an assignment of function to a putatively encoded protein. These comments also indicate that even in instances where a general functional assignment may be reasonable, the assignment does not provide information regarding the actual biological activity of an encoded protein and therefore patent claims drawn to such nucleic acids should be limited to method of use claims that are explicitly supported by the as-filed specification(s). These comments also state that if homology-based utilities are acceptable, then the nucleic acids, and proteins encoded thereby, should be considered as obvious over the prior art nucleic acids. On the other hand, one comment stated that homology is a standard, art-accepted basis for predicting utility, while another comment stated that any level of homology to a protein with known utility should be accepted as indicative of utility. *Response:* The suggestions to adopt a *per se* rule rejecting homology-based assertions of utility are not adopted. An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112). When the USPTO denies a patent, the Office must set forth at least a *prima facie* case as to why an applicant has not met the statutory requirements. The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' *per se* rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. *See, e.g., In re Brana,* 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did "not suggest an inherently unbelievable undertaking or involve implausible scientific principles' and where "prior art * * * discloses structurally similar compounds to those claimed by the applicants which have been proven * * * to be effective").

A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. *In re Oetiker,* 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *Fujikawa* v. *Wattanasin,* 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). The Office will take into account both the nature and degree of the homology.

When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no *per se* rule regarding homology, and each application must be judged on its own merits.

The comment indicating that if a homology-based utility could meet the requirements set forth under 35 U.S.C. 101, then the invention would have been obvious, is not adopted. Assessing nonobviousness under 35 U.S.C. 103 is separate from analyzing the utility requirements under 35 U.S.C. 101. When a claim to a nucleic acid supported by a homology-based utility meets the utility requirement of section 101, it does not follow that the claimed nucleic acid would have been *prima facie* obvious over the nucleic acids to which it is homologous. "[S]ection 103 requires a fact-intensive comparison of the [claim] with the prior art rather than the mechanical application of one or another *per se* rule." *In re Ochiai,* 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). Nonobviousness must be determined according to the analysis

in *Graham* v. *John Deere,* 383 U.S. 1, 148 USPQ 459 (1966). *See also, In re Dillon,* 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc) ("structural similarity between claimed and prior art subject matter, * * * *where the prior art gives reason or motivation to make the claimed compositions,* creates a prima facie case of obviousness") (emphasis added). Where "the prior art teaches a specific, structurally-definable compound [] the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." *In re Deuel,* 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

(20) *Comment:* Several comments indicated that in situations where a well-established utility is relied upon for compliance with 35 U.S.C. 101, the record should reflect what that utility is. One comment stated that the record should reflect whether the examiner accepted an asserted utility or relied upon a well-established utility after dismissing all asserted utilities. Another comment stated that when the examiner relies on a well-established utility not explicitly asserted by the applicant, the written record should clearly identify this utility and the rationale for considering it specific and substantial. *Response:* The comments are not adopted. Only one specific, substantial and credible utility is required to satisfy the statutory requirement. Where one or more well-established utilities would have been readily apparent to those of skill in the art at the time of the invention, an applicant may rely on any one of those utilities without prejudice. The record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities for related inventions. Thus, even when the examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities. Just as the examiner without comment may accept a properly asserted utility, there is no need for an examiner to comment on the existence of a well-established utility. However, the Guidelines have been revised to clarify that a well-established utility is a specific, substantial, and credible utility that must be readily apparent to one skilled in the art. Most often, the closest prior art cited and applied in the course of examining the application will demonstrate a well-established utility for the invention.

(21) *Comment:* Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment states that this requires the examiner to prove a negative. Another comment states that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility. *Response:* The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under § 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention.

(22) *Comment:* Several comments suggested that further clarification was required with regard to the examiner's determination that there is an adequate nexus between a showing supporting a well-established utility and the application as filed. The comments indicated that the meaning of this "nexus" was unclear. *Response:* The Guidelines have been modified to reflect that evidence provided by an applicant is to be analyzed with regard to a concordance between the showing and the full scope and content of the claimed invention as disclosed in the application as filed. In situations where the showing provides adequate evidence that the claim is supported by at least one asserted specific, substantial, and credible or well-established utility, the rejections under 35 U.S.C. 101 and 112, first paragraph, will be withdrawn. However, the examiner is instructed to consider whether or not the specification, in light of applicant's showing, is enabled for the use of the full scope of the claimed invention. Many times prior patents and printed publications provided by applicant will clearly demonstrate that a well-established utility exists.

(23) *Comment:* One comment states that the Office is using an improper standard in assessing "specific" utility. According to the comment, a distinction between "specific" and "general" utilities is an overreaching interpretation of the specificity requirement in the case law because "unique" or "particular" utilities have never been required by the law. The comment states that the specificity requirement concerns sufficiency of disclosure, *i.e.,* teaching how to make and use a claimed invention, not the utility requirement. The comment states that the specificity requirement is to be distinguished from the "substantial" utility requirement, and that the *Brenner* v. *Manson* decision concerned only a "substantial" utility issue, not specificity. *Response:* The comment is not adopted. The disclosure of only a general utility rather than a particular utility is insufficient to meet statutory requirements. Although the specificity requirement is relevant to § 112, it is not severable from the utility requirement.

> [S]urely Congress intended § 112 to pre-suppose *full satisfaction* of the requirements of § 101. Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention. As this court stated in *Diederich,* quoting with approval from the decision of the board:
>
> 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.' As the Supreme Court said in Brenner v. Manson:
>
> '* * * a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'
>
> *In re Kirk,* 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) (affirming rejections under §§ 101 and 112) (emphasis in original).

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility

requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

B. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 112, first paragraph.

1. Read the claims and the supporting written description.

(a) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(b) Ensure that the claims define statutory subject matter (*i.e.*, a process, machine, manufacture, composition of matter, or improvement thereof).

(c) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(1) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

(2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (*e.g.*, test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection.

(c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The §§ 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(1) Explicitly identify a specific and substantial utility for the claimed invention; and

(2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (*e.g.*, scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(b) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(c) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to

an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027288–0264–02]

RIN 0651–AB10

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" that were published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305–9035, by facsimile at (703) 305–9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at "stephen.walsh@uspto.gov"; or Linda Therkorn by telephone at (703) 305–8800, by facsimile at (703) 305–8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at "linda.therkorn@uspto.gov."

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.

Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the revision of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the "Discussion of Public Comments" in the "Utility Examination Guidelines" Final Notice, which will be published at or about the same time as the present Guidelines.

Responses to Specific Comments

(1) *Comment:* One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by "essential features of the invention." Another comment suggested that what applicant has identified as the "essential distinguishing characteristics" of the invention should be understood in terms of *Fiers* v. *Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name,